K081147

5. 510(k) Summary

VascularDesigns™

MAY 29 2009

Submitter's name:	Vascular Designs Inc
Address:	5655 Silver Creek Valley Road #512 San Jose, CA 95138
Phone:	408-230-5560
Fax number:	408-416-4116
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821 Email: grace@regulatoryspecialists.com

Date the summary was prepared: April 16, 2008

Name of the device:	IsoFlow
Trade or proprietary name:	IsoFlow
Common or usual name:	Infusion catheter
Classification name:	Catheter, percutaneous Continuous flush catheter
CFR Classification Reference	870.1250 870.1210
Class	Class II (two)
Product Code	DQY KRA

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Predicate Device Name	Submitted By	510k Reference #
DISPATCH™ Coronary Infusion Catheter	SCIMED	K932616
ISOLATE™ Infusion Catheter System	Lake Region Mfg. Co. Inc.	K913517

Description of the device:

The IsoFlow™ Infusion Catheter is a multi-lumen dual balloon catheter designed to isolate a specific treatment region from blood flow while allowing infusion of fluids into the region and perfusion of blood past the region. The exterior surface of the distal 120cm catheter length is treated with a hydrophilic coating.

The 2.4F IsoFlow™ Infusion Catheter System is intended to be used with guide catheters 4F (0.050") and larger, along with a 0.010" guide wire for positioning the catheter in the desired region. A standard Y-adaptor RHV provides for guide wire entry and saline flush into the main guide wire / bypass lumen of the catheter. Radiopaque markers at the distal tip and between the two balloons allow for final position adjustment under fluoroscopy guidance.

The two compliant balloons are inflated simultaneously using radiopaque fluid delivered via a single inflation lumen.

Physician specified infusion fluid through either the labeled infusion lumen or the labeled guidewire lumen is delivered via the 1-way stopcock connection. The mixture of infusion and radiopaque agents is delivered directly to the target region between the balloons, or out the distal tip respectively.

For infusion out of the sideport holes, retracting the guide wire to the radiopaque marker band proximal to both balloons allows blood to bypass the isolated target region via holes connecting the guide wire / bypass lumen with the catheter exterior. Complete removal of the guidewire allows delivery from the distal tip.

All components of the catheter system are provided sterile. Each device is intended for single use. Do not reuse or attempt to resterilize any component of the system.

Indications:

The IsoFlow™ Infusion Catheter is a multi-lumen dual balloon catheter designed to isolate a specific treatment region from blood flow while allowing infusion of fluids into the region and perfusion of blood past the region.

The device also has the ability to deliver physician specified fluids out the distal tip with or without inflation of the balloons.

Summary of characteristics of our device compared to the predicate device:

IsoFlow Catheter versus predicate devices

Parameter	DISPATCH™ Coronary Infusion Catheter K932616	ISOLATE™ Infusion Catheter System K913517
Intended Use	Substantially Equivalent	Substantially Equivalent
Physical Description	Substantially Equivalent	Substantially Equivalent
Anatomical Sites	Substantially Equivalent	Substantially Equivalent
Design	Substantially Equivalent	Substantially Equivalent
Materials	Substantially Equivalent	Substantially Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Designs
C/O Regulatory Specialists, Inc.
Ms. Grace Holland
Regulatory Consultant
3722 Ave: Sausalito
Irvine, CA 92606

MAY 29 2009

Re: K081147
Trade/Device Name: IsoFlow Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, DQY
Dated: May 4, 2009
Received: May 6, 2009

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K081147

Device Name: IsoFlow

Indications for Use:

The IsoFlow™ Infusion Catheter is a multi-lumen dual balloon catheter designed to isolate a specific treatment region from blood flow while allowing infusion of fluids into the region and perfusion of blood past the region.

The device also has the ability to deliver physician specified fluids out the distal tip with or without inflation of the balloons.

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081147

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